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(54) Marrow nail

(57) A marrow nail for insertion into the marrow cavity of a bone to fix a point of fracture consists of a tubular body of closed cross section made of nickel-titanium alloy and capable of assuming alternative shapes in dependence upon the memory effect. The shapes are distinguished by different radii of the circle enveloping the cross section of the nail and the cross section is a meandering or cushion shaped section with at least four corners separated by flat or concave wall portions which, upon passage through the temperature releasing the memory effect, is transformed to a circular or polygonal cross section with walls of less curvature.

Certain of the mathematical formulae appearing in the printed specification were submitted after the date of filing, the formulae originally submitted being incapable of being satisfactorily reproduced.

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FIG. 1a

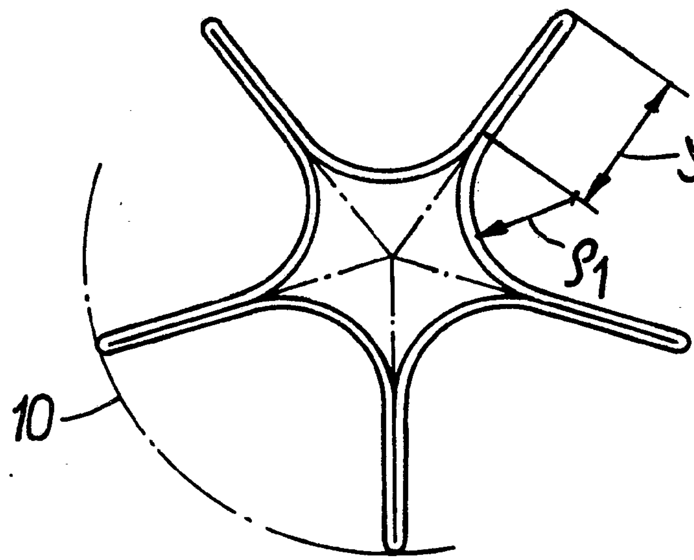


FIG. 1b

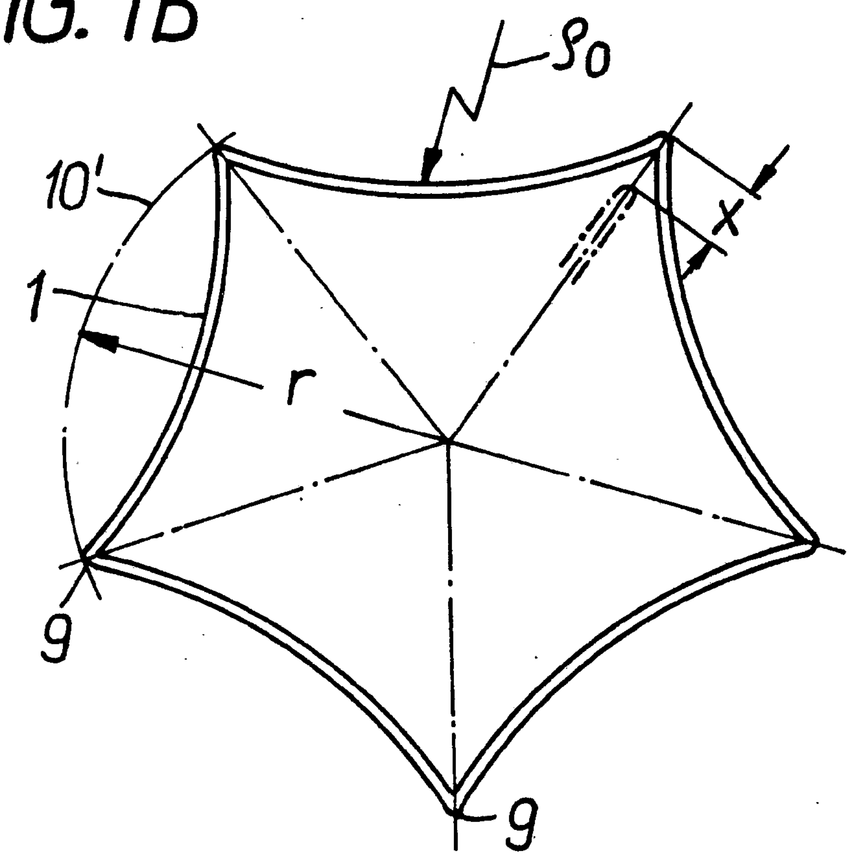


FIG. 2a

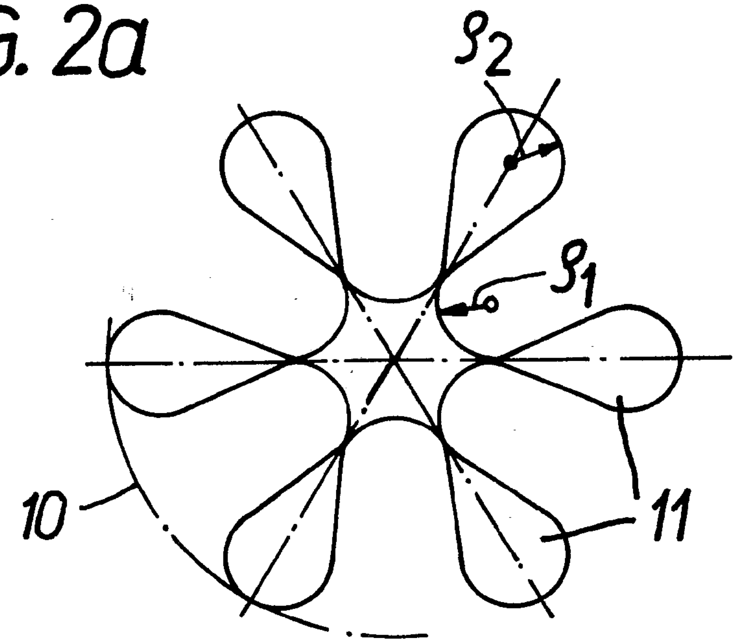


FIG. 2b

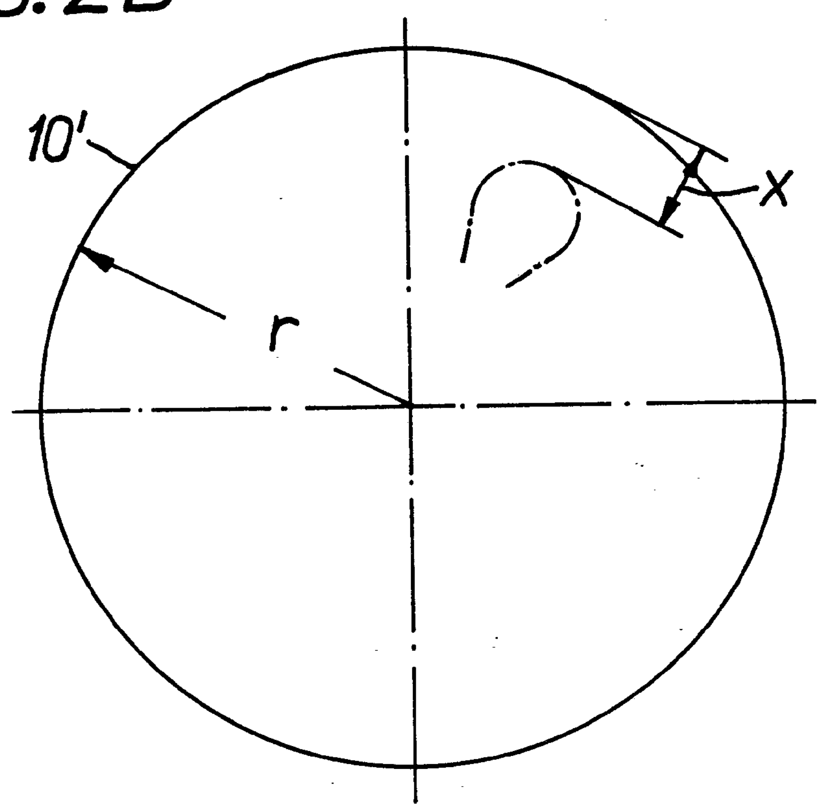


FIG. 3a

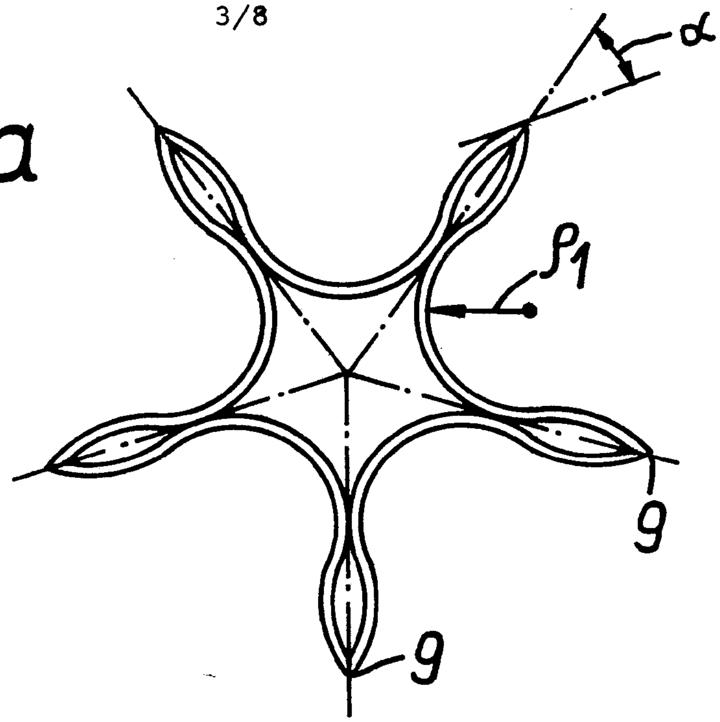


FIG. 3b

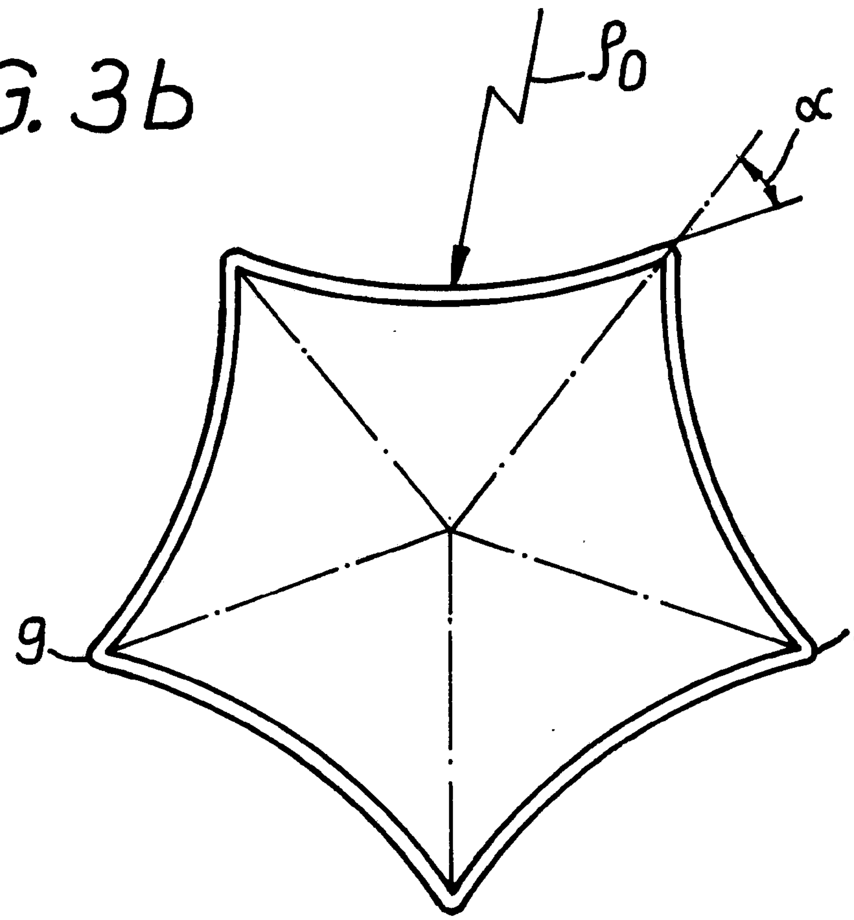


FIG. 4a

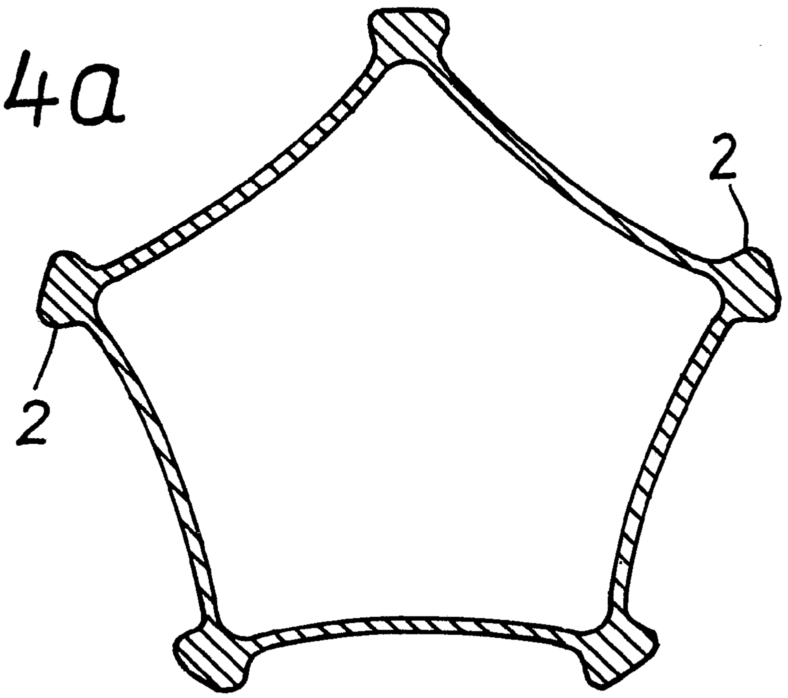


FIG. 4b

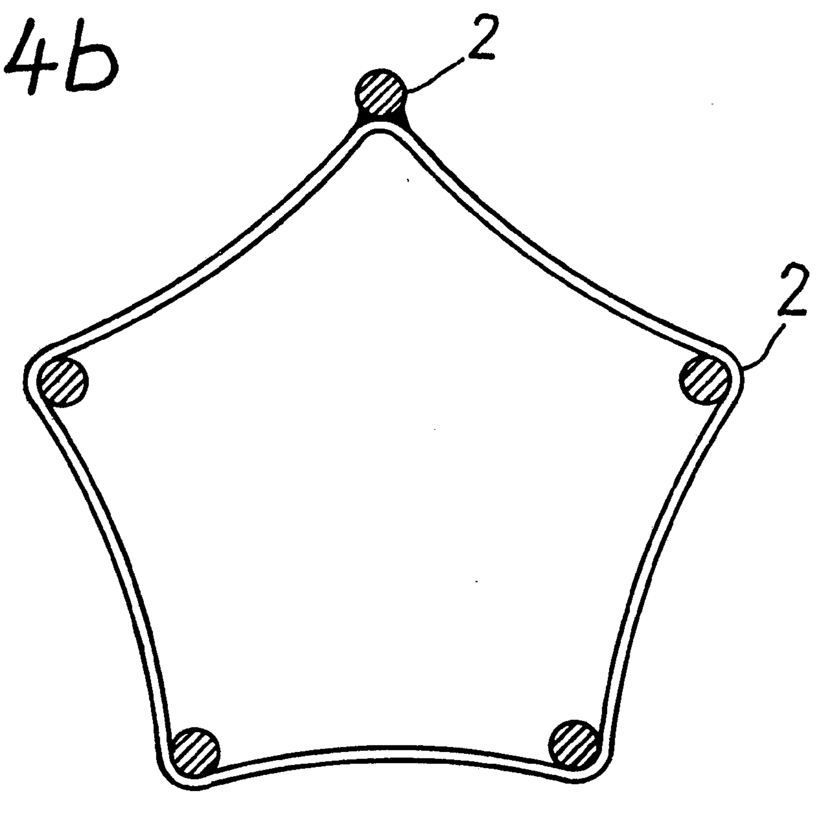


FIG. 5a

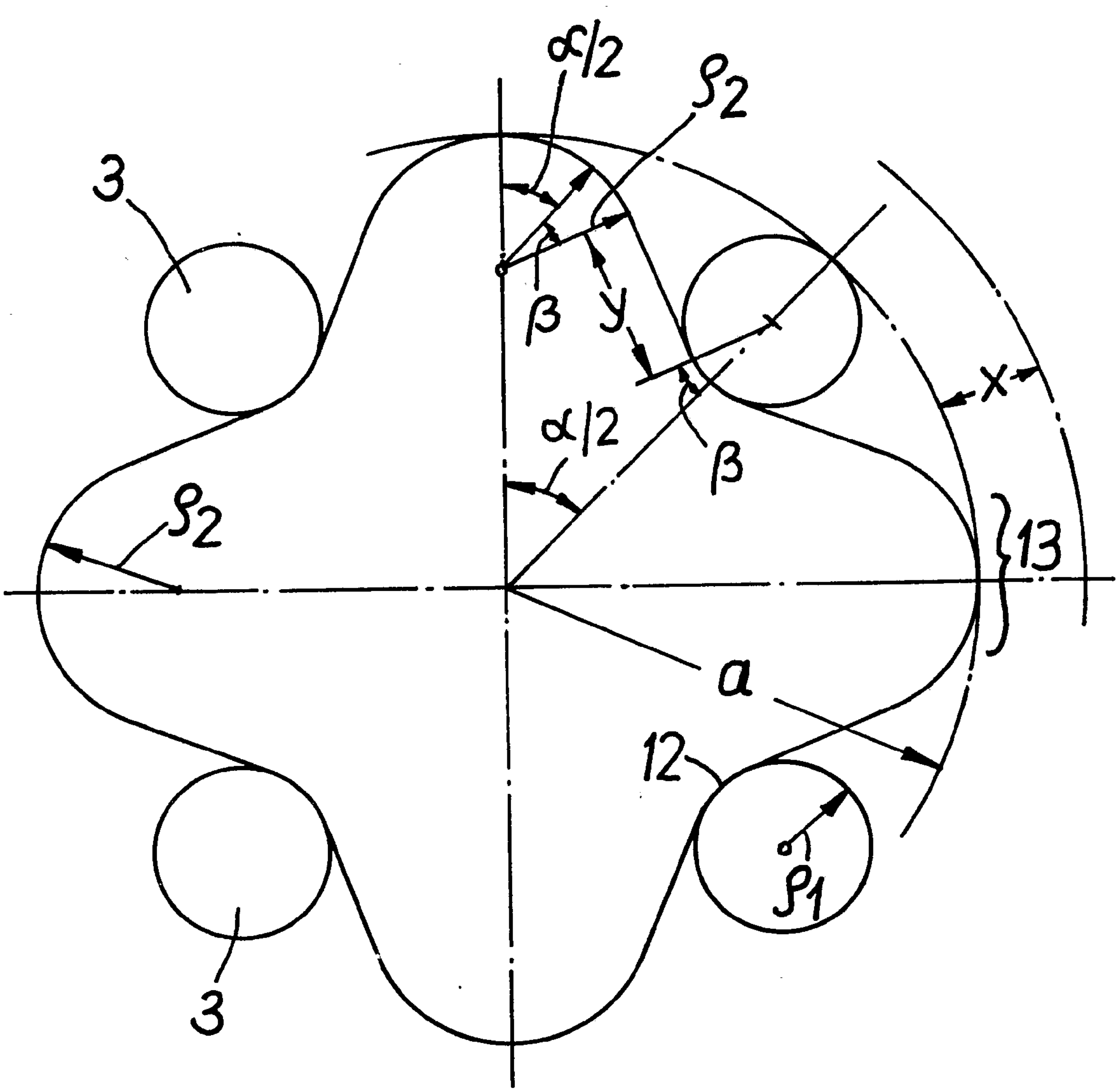


FIG. 5b

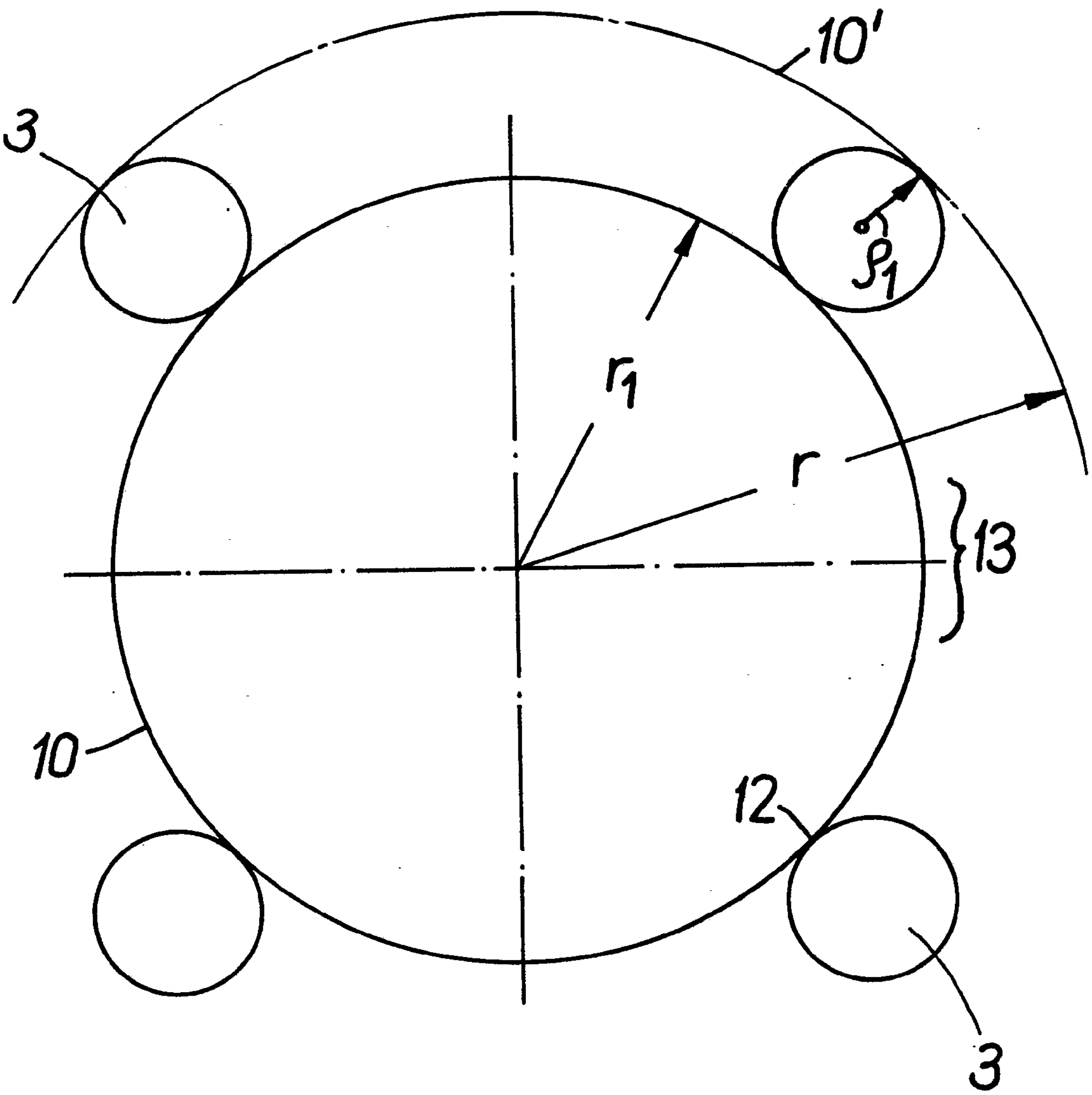


FIG. 6a

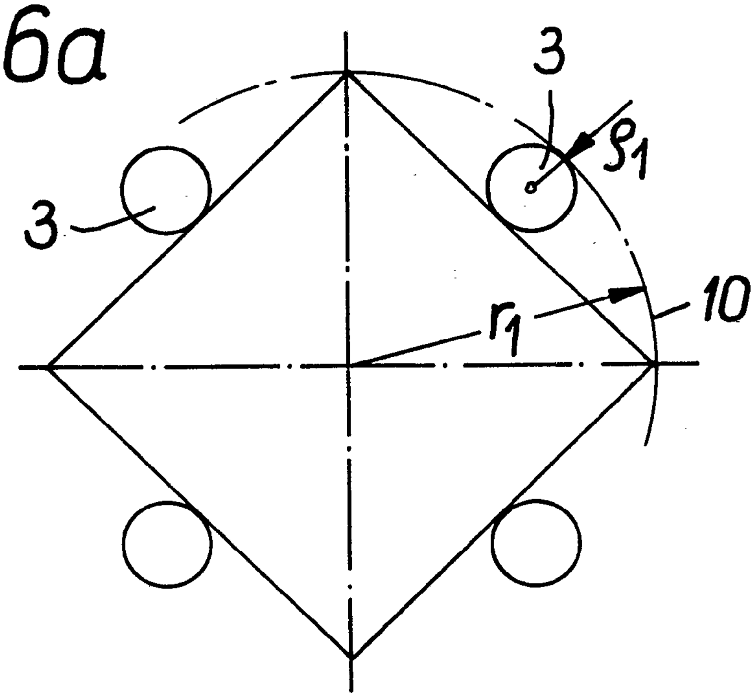


FIG. 6b

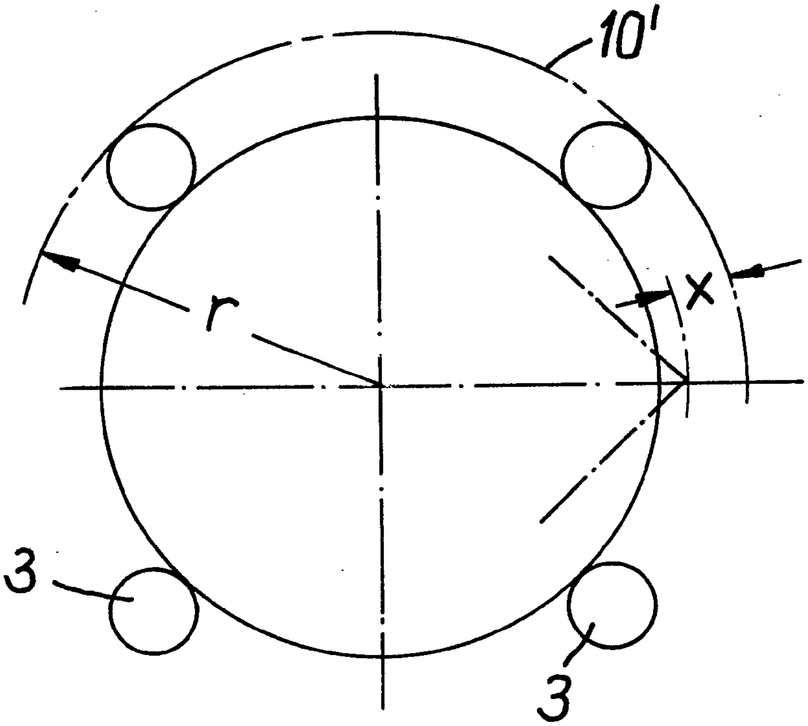


FIG.7

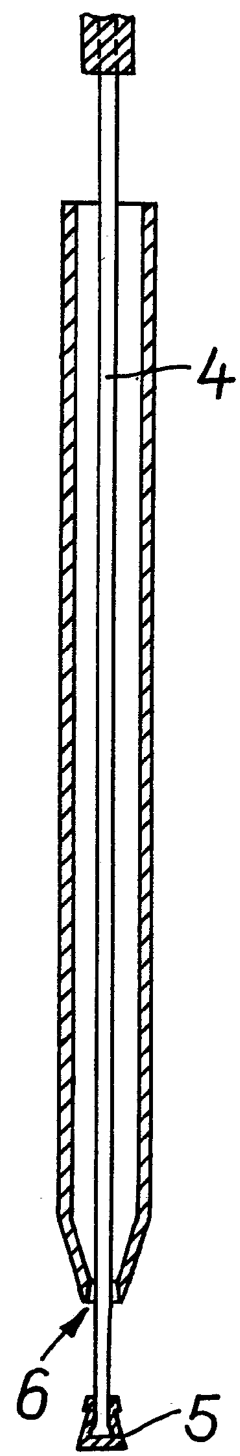
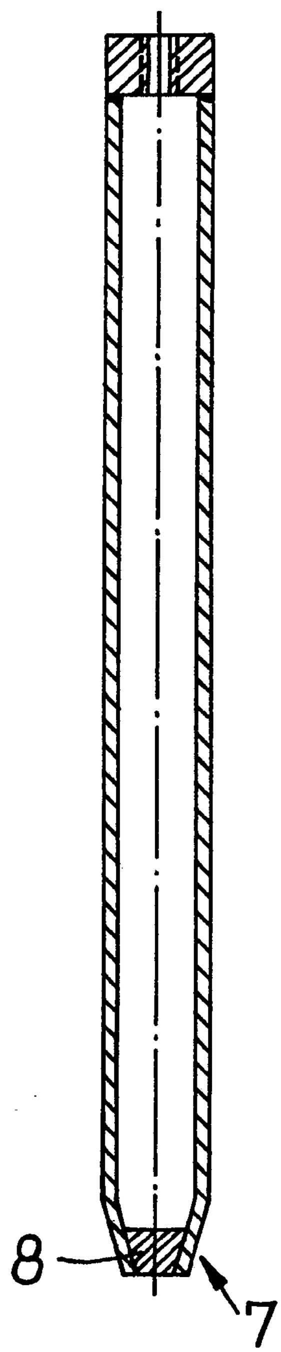


FIG.8



SPECIFICATION
Marrow nail

The invention relates to a marrow nail to be introduced longitudinally into a long hollow bone to fix a point of fracture. Such a marrow nail consists of a substantially closed but also partially twisted hollow body. The material used for marrow nails is in most cases stainless steel.

The marrow nails known in the art are generally of open cross-section having a shape reminiscent of a three-leaved clover leaf, the intention being that the nail having a diameter exceeding that of the bone cavity by 0.5 to 1 mm will be secured against rotation and, owing to the cross-sectional elasticity arising from its selected shape, can be fully and easily inserted into the bone. However the forces required to drive in the nail can be very large, which can sometimes cause breakage of the nail. There is also the risk with this type of nail that bone tissue can grow into the open longitudinal split in the nail, which can hinder removal of the nail after healing. Finally, with this type of nail there is no possibility of longitudinal anchorage so that the nail can wander both proximally and distally after introduction into the bone.

Much research has therefore been undertaken with a view to producing a marrow nail which can be anchored longitudinally after introduction into the bone.

Firstly DE-AS 1248228 describes a device which includes a hollow marrow nail insertable longitudinally into the cavity to be marked and within it a longitudinal axial tensioner held at both sides of the fracture. This device further requires a screw which passes transversely through the hollow marrow nail and which has to be inserted in a successive operational step for providing anchoring.

Similar spreaders are also described in DE—AS 2260839 and spreader dowels are described in DE—PS 2426281. This spreading procedure has however the disadvantage that it makes removal through healed parts of the bone difficult or impossible.

A marrow nail which can be spread along its whole effective length and which is formed of lamellar, thin walled overlapping plates which can be expanded by a gas or a liquid is also known (see DE-OS 2558484). The splitting of the wall of the nail into longitudinal lamellae to permit expansion leads however to a significant reduction in torsional stiffness of the nail, so that relative rotation of the fractured parts about the longitudinal axis of the nail cannot be effectively prevented. Also maintenance of the internal pressure involves difficulties so that the compression of the fracture surfaces is too small as it is provided solely by the transverse contraction effect of the nail.

Finally DE—OS 2821785 describes a compression nail in which anchorage is effected by a part of a claw insertable axially at the distal end and engages an axial projection on a proximal part of the claw. This compression nail does not provide a positive connection between the nail and the wall of the bone.

Moreover the above-described marrow nails have above all the disadvantage that larger forces are required for their introduction and removal, which leads to the danger of injuring the bone, that there is no or insufficient longitudinal anchorage of the marrow nail in the bone, that extensive boring out of the bone is necessary which can lead to fat embolism and that the insertion pressure must generally be very high and is uncontrollable after the nail has been introduced, while relative rotation of the fracture parts cannot be prevented with certainty. Some of the known marrow nails have too little strength, stiffness against bending and/or torsional stiffness. Also handling of the marrow nails is often complicated and difficult.

It is also known that so-called memory alloys, i.e. Ni—Ti alloys consisting of 55% Ni, the rest Ti, can perform mechanical work when heated subsequent to a preliminary deformation. This effect, which arises from structural changes, caused by a tension-inducing martensitic transformation which is reversible, is released when after plastic deformation of this alloy by heating above a temperature specific to the material it returns to the original form it had before the deformation. The return takes place in a temperature range which depends very much on the composition of the alloy and can be varied by addition of iron, cobalt, manganese, aluminium, gold or zirconium.

The knowledge that thermally controlled forces can be released by suitable choice of the composition of memory alloys has already been utilised in a bone plate which is screwed to the bone on both sides of the fracture and, after heating, exerts by contraction by means of the memory effect a tension force on both sides of the fracture towards the fracture (U.S. specification 3786806). DE—OS 2703529 describes the use of implants, such as marrow nails, osteosynthesis plates, prothesis parts and the like of memory alloys. It is also proposed to introduce bone nails of a memory alloy in the normal way into long cavities and to expand them in the bone by use of the memory effect. These marrow nails also give insufficient anchorage.

The object of the invention is to provide a marrow nail having none of the above disadvantages and which can be easily and firmly fixed in the bone. This object is achieved by a marrow nail having the characteristics set out in claim 1. The special advantage of the marrow nail according to the invention is that owing to its closed form it has a high torsional stiffness and allows no growth of bone tissue into a slot in the nail and also has the high transverse elasticity of an open section. These advantages are combined with the possibility of using the memory effect to an optimal extent so that

after release of the memory effect the outer surface of the nail will lie firmly against the inner wall of the bone, so ensuring both good stabilisation and good compression. In contrast to the previously proposed marrow nails made of a memory alloy the cross-sectional form of the nail according to the invention results by release of the memory effect in a substantially greater increase in diameter of the nail so that insertion and removal can be effected without application of force.

According to a feature of the invention the marrow nail may be double-walled if necessary with a shaped part inserted between the walls. This gives the nail increased stiffness after insertion into the bone. The cavity formed by the double walls can also serve for the introduction of gaseous and/or liquid media. The gases or liquids can also be pre-heated or pre-cooled for improvement of the mechanical properties of the nail and for release of the memory effect inherent in the nail.

To facilitate guiding of the nail during introduction into the bone, the nail may have an axial closable opening to receive a guide. This, according to a further feature of the invention may be a lance carrying at its tip a cone of plastics material, by which the opening in the nail may be closed by withdrawal of the guide. As a further feature of the nail according to the invention it may have in cross-section concave outer walls with a fine irregular wave profile. This wave profile may most easily be provided by applying to the outer walls of the nail pieces of sheet or round wire which form corresponding protrusions.

Further improvement of the stability of the nail may be provided by reinforcing its edges.

Embodiments of the invention are shown in the drawings, in which:—

Figs. 1 to 3 show cross-sections of marrow nail in the condition before (Fig. *a* in each case) and after (Fig. *b*) release of the memory effect,

Figs. 4*a*, *b* show a marrow nail with five reinforced edges,

Fig. 5 is a cross-section showing a marrow nail with welded-on round wires which becomes circular (*b*) after release of the memory effect,

Fig. 6 shows a marrow nail which is rectangular before release of the memory effect, has welded-on round wires and becomes circular after release of the memory effect (*b*),

Fig. 7 is a longitudinal section of a marrow nail including a guide, and

Fig. 8 is a longitudinal section in which the opening at the tip of the nail has been closed by a cone of plastics material.

The illustrated marrow nails according to the invention all have a closed outer wall. This can consist of a hollow section, for example a rectangular tube, or in another appropriate case of a sheet bent to circular form and having on part at least of the periphery two or more overlapping layers of sheet. The cavity in the nail may be closed or open at the ends. The disadvantage of the closed section is that on insertion of the nail there is high resistance to radial compression from all sides, i.e. little transverse elasticity. This disadvantage may be removed by shaping the nail, the construction of the portions of the nail or by choice of the material. The form of cross-section of the hollow nail shown in Fig. 1 is such that the wall 1 consists wholly or partially of concave arcs, so producing a star shaped contour with rotational symmetry. Upon rotation of the section through an angle $2\,\pi/n$, where n is the number of edges 9, the shape becomes congruent with its shape before rotation. The selection of part cylindrical wall portions of radius ρ_0 in Fig. 1*b* has the advantage that these portions may be formed by radial deformation (Fig. 1*a*) by means of a part-circular punch of smaller radius ρ_1 and then undergo uniform deformation in bending only, i.e. they are uniformly stressed and utilised. The inner and outer fibres have therefore all been subjected to the same peripheral elongation. The nail according to the invention is made of an alloy consisting of 55% Ni and 45% Ti so that the nail may be transformed by heating from the shape of Fig. 1*a* to that of Fig. 1*b*. The star shaped cross-section permits, notwithstanding the closed section, a particularly effective change in the diameter of the circle 10 or 10′. The change in diameter can be calculated when the symmetry number n and radius ρ_0 are known and also the permissible change in elongation of the edge fibres of sheet on changing from one of the configurations shown to the other and back again.

In the following calculation the sheet thickness is assumed to be negligibly small. In this case the following relationships apply:—

(a) for the change in diameter, D=2r

$$\frac{X}{r} = \frac{\Delta D}{D} = 1 - \frac{\rho_0}{r}\ \mathrm{arc\ sin}\left[\frac{r}{\rho_0{}^{1}}\ \sin\ \frac{\pi}{n}\right]$$

$$+ \frac{\rho_1}{r}\left[\frac{\pi}{2}\left(1-\frac{2}{n}\right) - \frac{1}{\tan\frac{\pi}{n}}\right]$$

(b) for the ray length in relation to the radius r

$$\frac{y}{r} = \frac{\rho_0}{r} \arcsin\left[\frac{r}{\rho_0} \sin\frac{\pi}{n}\right] - \frac{\rho_1}{r} \cdot \frac{\pi}{2}\left(1 - \frac{2}{n}\right)$$

In the above *r* is the radius of the circle surrounding the cross-section in the form shown in Fig. 1*b*,

$$x = \frac{\Delta D}{2}$$

is the diminution in this radius upon change to the configuration of Fig. 1*a*.

When the sheet thickness *t* is given, the change in elongation of the edge fibres in the middle range of the cylindrical parts is given by

$$\left|\Delta\varepsilon\right| = \frac{t}{2}\left(\frac{1}{\rho_1} - \frac{1}{\rho_0}\right)$$

If a permissible change of elongation, e.g. that arising from activation of the memory effect, is given so if ρ_0 is known, the radius ρ_1 and therefore the form shown in Fig. 1*a* can be calculated.

In the limiting case, i.e. when $\rho_0 \to \infty$, representing the polygon corresponding to the configuration shown in Fig. 1*b*

$$\frac{\rho_0}{r} \arcsin\left[\frac{r}{\rho_0} \sin\frac{\pi}{n}\right]$$

is to be replaced by $\sin\frac{\pi}{n}$.

As a special example the following cases are considered:

t=0.8 mm 1 ρ_0=r
D=11 mm 2 $\rho_0 \to \infty$ (Polygon)
$\Delta\varepsilon$=0.1=10%

Symmetry number:	*Case 1, ρ_0=r*			*Case 2, $\rho_0 \to \infty$*		
n	ρ_1/r	y/r	x/r	ρ_1/r	y/r	x/r
3	0,42105	0,82674	negative	0,72727	0,48523	0,09488
4	"	0,45471	0,12424	"	0,13591	0,13682
5	"	0,23149	0,18899	"	negative	0,09665
6	"	0,08268	0,18804	"	negative	0,00193
7	"	negative	0,14930	"	negative	negative

The above table shows that certain forms cannot be realised in practice (i.e. those with negative values for x/r or y/r) and that others result in particularly large variations in diameter. In particular for the star-shaped nail shown in Fig. 1*a* and *b*, when ρ_0=r a change in diameter of almost 19% is obtained.

The nail may have other forms of cross-section, i.e. the meandering form shown in Fig. 2*a* which, after completion of heating, changes to a circular form of radius r as shown in Fig. 2*b*. There are many variations in diameter between the shapes shown in Fig. 2*a* and *b* even though they do not attain the effect of the star shape shown in Fig. 1 with concave portions. The meandering form shown in Fig. 2*a* has six projections, each of radius ρ_2, and connecting pieces having the same radius ρ_1.

Another nail according to the invention is shown in Fig. 3. The shape shown in Fig. 3*b*, to which the outer wall of the nail has concave arcuate portions of radius ρ_0, can be changed by use of the memory effect to the shape shown in Fig. 3*a*. Upon this change the edges of the nail form leaf-like parts, separated by wall portions of radius ρ_1. The memory nail shown in Fig. 3 undergoes strong local deformation at the edges 9 with maintenance of the angle α formed by prolongation of the wall sections meeting at an edge.

The nail cross-sections shown in Figs. 4*a* and 4*b* differ from the previous cross-sections in having reinforced corners or edges 2. It is possible, as in Fig. 4*a*, so to shape the edges that they have widened abutment surfaces which reduces the surface pressure between the bone and the nail, and also large radii of curvature at the edges of the nail. As shown in Fig. 4*b* the reinforcement of the edges can be provided inside rather than outside the nail. In the simplest cases welded-on pieces of tube or wire can be used. The embodiments shown in Figs. 4*a* and 4*b* have the advantage of increasing the bending stiffness and load bearing capacity of the nail by provision of material at the most outlying portions of the periphery while retaining the transverse elasticity. This is also possible when a nail corresponding to Fig. 4*a* is provided in which the sheet material is heavily flanged at the edges so that an increased abutment surface is produced.

Another advantageous embodiment of the nail is shown in cross-section in Fig. 5. The cross-section shown in Fig. 5*b*, with welded-on round rods 3 or increase in thickness with an external radius can be transformed by use of the memory effect into the form shown in Fig. 5*a*, in which the rods 3 or thickened portions move radially inwards to provide an envelope radius *a*. This is possible because the parts of the wall of the nail at the lines 12 of welding to the rods 3 or thickened portions move radially inward, while the intervening portions 13 of the wall move radially outwards to produce the cushion shape shown in Fig. 5*a*. The changes in diameter of the envelope circle for the forms shown in Figs. 5*a* and 5*b* are determined by the following geometrical relationsips:

$$\frac{x}{r} = \frac{\Delta D}{D} = 1 - \frac{a}{r}$$

The values of

$$\frac{a}{r}$$

and the angle β can be calculated from equations

$$\frac{a}{r}\left[\cos\beta - \cos\left(\frac{\alpha}{2}+\beta\right)\right] + \frac{\rho_2}{r}\cos\left(\frac{\alpha}{2}+\beta\right) - \frac{\rho_1}{r}\cos\beta = \frac{\rho_1}{r}+\frac{\rho_2}{r}$$

and

$$\frac{a}{r}\left[\sin\beta - \sin\left(\frac{\alpha}{2}+\beta\right)\right] + \frac{\rho_2}{r}\sin\left(\frac{\alpha}{2}+\beta\right) - \frac{\rho_1}{r}\sin\beta = \beta\left(\frac{\rho_1}{r}+\frac{\rho_2}{r}\right) + \frac{\alpha}{2}\left(\frac{\rho_2}{r} - \frac{r_1}{r}\right)$$

when $\rho 1/r$ and $\rho 2/r$ are known. These equations ensure maintainance of the arc length of the nail on transformation from the form of Fig. 5*b* to that of Fig. 5*a*. In calculating the rim elongations of value $\Delta\varepsilon$ on this transformation the following relations apply

$$|\Delta\varepsilon| \geqq \frac{t}{2}\left(\frac{1}{\rho_1} + \frac{1}{r_1}\right)$$

and

$$|\Delta\varepsilon| \geqq \frac{t}{2}\left(\frac{1}{\rho_2} - \frac{1}{r_1}\right)$$

t is the sheet thickness of the tube forming the nail and $\Delta\varepsilon$ the permissible elongation, i.e. that available from the memory effect. From the abbreviation

$$\varepsilon^* = /\Delta\varepsilon/ \cdot \frac{2r}{t}$$

the limiting values of the radii r_1, ρ_1 and ρ_2 can be calculated as follows

$$\frac{r_1}{r} = \frac{1}{2}\left(1 - \frac{\rho_1}{r}\right)$$

and therefore

$$\frac{\rho_1}{r} \geqq \frac{1}{2}\left[\frac{\varepsilon^* - 1}{\varepsilon^*} \pm \sqrt{1 - \frac{6}{\varepsilon^*} + \frac{1}{\varepsilon^* 2}}\right]$$

and

$$\frac{\rho_2}{r} \geqq \frac{1 - \frac{\rho_1}{r}}{2 + \varepsilon^*\left(1 - \frac{\rho_1}{r}\right)}$$

The practically useful value for

$$\frac{\rho 1}{r}$$

is to be selected from the two solutions. The linear portion y is then to be computed from the formula

$$\frac{Y}{r} = \frac{r_1}{r} \cdot \frac{\alpha}{2} - \frac{\rho_2}{r}\left(\frac{\alpha}{2} + \beta\right) - \frac{\rho_1}{r}\beta$$

A very rough approximation of the minimum value of the change in diameter can easily be obtained when one abstains from the limitation of the elongation and assumes that ρ_2 and β are zero. A wavelike profile such as that in Fig. 5*a* is transformed into a polygon and one can state,

$$\alpha \text{ being} = \frac{\pi}{2n}$$

$$\frac{r_1}{r} = \frac{1}{1 + \frac{\pi}{n} \tan \frac{\pi}{2n}}$$

$$\frac{2\rho_1}{r} = \frac{\pi}{n} \cdot \frac{\tan \frac{\pi}{2n}}{1 + \frac{\pi}{n} \tan \frac{\pi}{2n}}$$

$$\frac{x}{r} = 1 - \frac{\pi}{n} \cdot \frac{1}{\sin \frac{\pi}{n}} \cdot \frac{1}{1 + \frac{\pi}{n} \tan \frac{\pi}{2n}}$$

The distance y is then

$$\frac{y}{r} = \frac{\pi}{n} \cdot \frac{r_1}{r} = \frac{\pi}{n} \cdot \frac{1}{1 + \frac{\pi}{n} \cdot \tan \frac{\pi}{2n}}$$

The lower limits for the change in diameter are then

n	$\frac{\rho_1}{t}$	$\frac{x}{r} = \frac{\Delta D}{D}$
2	0,61102	0,38898
3	0,37679	0,24642
4	0,24547	0,16192
5	0,16954	0,11227
6	0,12304	0,08165

Here the arc length of the tube wall is maintained. Figs. 6*a* and *b* show the form when n=4.

The particular advantages of the nail according to the invention reside in the high torsional stiffness and the high capacity to take torsion loads of the closed cross-section in contrast to the open of the same cross-section, in the prevention of growth of the bone into the interior of the nail due to the closed cross-section and consequent ease of removal and in the large change in diameter of this hollow nail. This form is also particularly suitable for ensuring rotational stability of the fragments. There is also the possibility of further expansion of the nail by application of pneumatic or hydraulic internal pressure. Also by insertion of a guide into the nail it is possible to achieve further expansion and additional increase in load bearing capacity and stiffness.

It is also possible to make the wall of the nail very thin which permits even greater change in diameter and to strengthen it by insertion of an inner nail. The special advantage is that by warming the nail by means of hot liquid or gas it can be flushed internally with good transfer of heat and without contaminating the surrounding tissue. To this end a special fitting can be provided at one end, e.g. a screw-threaded bore.

As shown in Fig. 7, the nail is advantageously introduced by means of a guide lance 4, over which is pushed the nail preformed to the shape of Fig. 1*b*, 2*b*, 3*b*, or 5*b*. The lance carries on its point a cone 5 of plastics material, which automatically closes the opening in the head 6 of the nail when the lance 4 is withdrawn and then rests in a securing groove. As shown in Fig. 8 it is also possible to close the opening in the head 7 of the nail by a cone 8 of plastics material introduced from the inside.

The nail may, after checking its correct seating, e.g. by an iconoscope, be warmed by hot fluid or by a contact heating electrode or inductively, it then resumes its expanded configuration shown in Figs. 1*b*, 2*b*, 3*b*, 5*b* so that it is firmly anchored in the prepared marrow channel and stabilises the fracture. The rear end of the nail can then be closed by a cone of plastics material or may remain open.

It is particularly advantageous in removing the nail that the nail, being made of a memory alloy, will reduce in external diameter when cooled so that the clamping effect is reduced and removal of the nail is easy.

It is also possible to warm only part of the length of the nail so that the memory effect is utilised in certain determined zones only. This can be done when a compression in the longitudinal direction is desired. The nail is then also preformed by stretching longitudinally and can have at its ends removable or fitted anchorage parts. The anchoring at the ends is removed after insertion and longitudinal compression then effected by warming in the middle region. Similar advantages can be achieved with nails which have overlapping wall portions in one of the conditions.

Claims

1. A marrow nail, for introduction into the marrow cavity of a bone, preferably a long bone, to fix a point of fracture which consists of a substantially closed but also partly twisted tubular body, characterised in that the nail consists of a nickel-titanium alloy containing 54—56% by weight of nickel, the rest titanium, and owing to plastic deformation is capable of assuming as the result of the known memory effect and in dependence on temperature two possible forms, which are differentiated by different radii of the smallest circle overlapping the cross-section of the nail and in that the nail has a multi-cornered meandering or cushion shaped cross-section having at least four corners with concave or plane outer walls which, upon exceeding or falling below the temperature releasing the memory effect, is expanded into circular or multi-cornered cross-section with concave walls of less curvature.

2. A nail according to claim 1, characterised by a double walled construction.

3. A nail according to claims 1 and 2, characterised by insertion of a guide into its hollow interior or between the double walls.

4. A nail according to claims 1 and 2, characterised by a closed interior which can be filled with or traversed by gaseous and/or liquid media through an end fitting.

5. A nail according to claims 1 to 4, characterised in that the otherwise closed tip of the nail has an axial closable opening for a guide for the nail.

6. A nail according to claim 5, characterised in that the guide is a lance carrying on its tip a cone of plastics material by which the opening in the nail can be closed by withdrawing the lance.

7. A nail according to claims 1 to 6, characterised in that the concave outer walls of the cross-section have a fine irregular wave profile.

8. A nail according to claim 7, characterised in that the wave profile of the outer walls is irregular and the projections are formed by fitted pieces of sheet or round wire.

9. A nail according to claims 1 to 8, characterised in that the edges of the nail are reinforced.

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